Case: 1:17-md-02804 Doc #: 1864-41 Filed: 07/19/19 1 of 4. PageID #: 58971

EXHIBIT KK

21-0102

Health and Wellness Manual



Cage/Vault Orderfilling

Purpose

To outline the process used to receive, store, secure, and fill store orders for control drugs from the control cage or vault area.

Resources

Links	Resources
Procedures	
21-0105	Orderfilling
21-0201	Purchase Order Processing
Forms	
	222 Form
WMW-1360	Do Not Pull Recall Tag
WMW-2306	Control Pharmaceutical Item Storage Log
Reports	
DCB341	Breakpack Activity for Area
DCB371	Breakpack Slot Quantity at End of Batch Report
DC0171	Slot Contents Report
Items Needed	
	Walmart Purchase Order (PO)

Procedures

Notice

- Keep control drugs in a secure cage or vault area separate from other inventory.
- Store and process control drugs (Classes CIII, CIV, and CV) in a DEA approved cage.
- Store and process control drugs (Class CII) in a DEA approved vault.

Receiving

When a shipment is accepted in Receiving, the Receiving Clerk identifies the control drugs, which are moved directly to the cage or vault area.

The process for receiving control drugs is the same as for non-controls, but receiving control drugs must be done inside the controlled area of a cage or vault. The Receiving Clerk marks control drugs listed on the PO with a red "C" to identify them as a control item (this is excluding DC 6045). Refer to 21-201 PO Processing procedure.

Replenishment

Replenishment is the process of moving freight from reserve slots to prime slots for orderfilling. Replenishment is necessary for items received and keyed to a reserve slot location. Each Distribution Center (DC) designates specific associates to handle replenishment. Refer to 21-105 Orderfilling procedure.

Note: Replenishment is not necessary for items received and keyed directly into the prime slot.

The orderfilling process involves:

- Picking
- Verifying and Sealing
- Weighing

Cage Orderfilling

Select and pull merchandise from the prime slots to fulfill the stores order. Make sure the merchandise matches the order before it is sent out of the cage/vault.

Note: Refer to 21-0105 Orderfilling procedure for details.

Once the orderfiller completes the store orderfilling process, move the container to the verifying station.

Note: At DC 6001, orderfilling is done with an A-Frame picking system and a pick-to-light system.

Verifying and Sealing

After the picking process, a different associate verifies the order for accuracy.

Use the following software to complete this process:

- Knapp (used by DC 6001 only)
- Reddwerks (used by all other pharmacy DC's)

The system compares what the associate scans with what is expected to be in the container and reconciles the differences.

As the store order is verified, all product must be placed into a sealable plastic bag. As orders are completed, the plastic bags must be sealed.

Note: DC 6045 must include the blue copy of Form 222 and a copy of the invoice inside the bag.

Weighing

When the bag of control drugs is sealed, it must be weighed. The DC system tracks the bag's weight and keeps it for future reference. Each outbound container must be weighed before leaving the cage/vault.

Shipping

When the weight is recorded, the bag of control drugs is ready to be packaged for shipment to the store. If there are non-control items on order for the store, it can be shipped along with the bag of control drugs in the same box.

Inventory

An inventory check is performed by the cage/vault associates, using the end of day inventory report, at a minimum of once daily. A blind count of each prime slot is taken and a different associate denotes the count on the report. This count includes all controlled inventory.

Once the count is verified, mark the report as correct by circling the quantity. Repeat this process for each line until all items are counted and verified as correct.

Special Inventories

There are two special inventories taken of all control drugs.

- Year Ending Inventory Taken at the close of business on last calendar work day of each year.
- Biennial Inventory Taken every two years following the date of the initial inventory.

These inventories include all stock in the cage or vault at the close of business on the day the inventory is taken, including freight received the day of the special inventory.

At least one manager must be present to oversee the inventory verification process.

The DC keeps a copy of the special inventory and forwards a copy to the Home Office (HO). Send the HO copy to the attention of the Director of Pharmacy Logistics.

Inventory Record Retention

Retain all inventory records (which include the DCB341, DCB371 and DC0171) for three years (excluding the biennial inventory that must be retained forever).

Not Saleable Quarantine Inventory

Use the area inside the cage/vault clearly marked as the Quarantine area to separate all damaged or non-shippable control items, which includes, but is not limited to:

- Expired items
- Items with damaged bottles
- Items with broken seals
- Items missing label information, such as:
 - Expiration date
 - Lot number
 - Product name
 - o National Drug Code (NDC) number

As soon as an item is determined to be not saleable, move it to the Quarantine area in the cage/vault and keep the item there until it is returned to the supplier or sent to a Control Drug Return Goods processor. If any additional space is required, place a temporary quarantine tag on the product to clearly identify it as quarantined, also tag with a WMW-1360 Do Not Pull Recall Tag.

Note: Check every prime slot location weekly for short dated or out of date merchandise. Perform this task with the daily inventory. As each prime slot location is counted, check the expiration date of the product. This is done until the dates on all items are checked.

Storage of Overstock Inventory

In the unusual event that the control cage has met capacity, Home Office Operations and Regulatory Affairs must grant the DC approval to store controlled pharmaceutical items outside of the control cage. The DC must notify the Home Office Operations team of the amount of pallet(s) and item(s) that need to be stored outside of the cage and the amount of time that controlled item(s) need to be stored outside of the cage. The Operations team will notify Regulatory Affairs of the request. Once both teams have approved, the Operations team will notify the DC. The following guidelines must be followed while storing controlled pharmaceutical items outside of the control cage:

- The AP Manager of the building must be notified when items are stored outside of the cage.
- Only top level of reserve racks that are under camera view may be designated as the appropriate storage for controlled pharmaceutical.
- All top level reserve slots used for storing control pharmaceutical items must be frozen in the system. Unfreezing of these reserve(s) require DC management approval.
- Items that will be stored out of the cage must shrink-wrapped top to bottom.
- The WMW-2306 Control Pharmaceutical Item Storage Log must be filled out and maintained until the item(s) is moved back to the cage. The log needs to be located in the QA Manager's Office.
- A member of management must verify daily each pallet in the rack to ensure the shrink-wrap is intact. This is documented on the WMW-2306 Control Pharmaceutical Item Storage Log.
- Any pallet stored outside of the cage must be for storage only. If a pallet is needed for replenishment, it must be relocated to the cage before the shrink-wrap is cut and must remain in the cage.